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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Proposed Regulations for Registration of Food Facilities
FDA Docket No. 02N-0276

The American Plastics Council (APC) and the Polystyrene Packaging Council (PSPC) submit these comments on the Food and Drug Administration's (FDA) proposed regulation for Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). APC and PSPC appreciate the important role FDA plays in the protection of the food supply in the United States, and the difficult task it has in implementing the Bioterrorism Act, but this proposed regulation does not further that important purpose. FDA's focus on "food" rather than "food for consumption" as set out in the Bioterrorism Act has caused the regulation to miss the mark. FDA's proposed definition is overbroad, as it would expose packaging and other food contact substance manufacturers and suppliers to the registration requirements. FDA's definition ignores the express language of the statute, in violation of well-established principles. FDA has underestimated the burden this will cause for industry, and has not shown that it will serve any benefit in increasing the safety of the food supply. Accordingly, as explained in these comments, APC and PSPC request that FDA amend its proposed regulation to focus more properly on "food for consumption," and exclude packaging manufacturers, other food contact substance manufacturers, and their suppliers from the registration requirements. Doing so is consistent with the Bioterrorism Act, congressional intent, and FDA's public safety mandate.

Respectfully submitted,

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These comments are submitted by the American Plastics Council (APC) and the Polystyrene Packaging Council (PSPC), a business unit of APC. APC is a major trade association for the U.S. plastics industry. It is comprised of 23 of the leading resin manufacturers, plus one affiliated trade association representing the vinyl industry. APC's membership represents more than 80 percent of the U.S. monomer and polymer production and distribution capacity. PSPC represents the full scope of the polystyrene industry, from resin producers to finished product fabricators. Because a substantial portion of the production of the member companies of both organizations may be used in contact with food, APC and PSPC are submitting these comments to ensure that the Food and Drug Administration (FDA) considers the full impact of its proposed regulations on the industries.

APC and PSPC appreciate the important job FDA is undertaking in protecting the safety of the United States food supply. The proposed regulations, however, will impose a very large burden

on APC and PSPC's member companies, with only a very limited and theoretical increase, if any, in the safety of the food supply. In proposing that the registration requirements apply to packaging material and other food contact article facilities and, necessarily, their suppliers, FDA has not followed Congress' express intent, and has created an unreasonable and unjustified burden on the industry. FDA must follow the express language of the statute, and give effect to each word therein.

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) provides that FDA shall by regulation "require that any facility engaged in manufacturing, processing, packing or holding food for consumption in the United States be registered [with FDA]." Congress modified "food" with the term "for consumption" in describing the type of facilities that are subject to the registration requirement. In its proposed regulation, FDA has ignored this explicit language, in direct contravention to the well established principle that each word in a statute has significance. FDA's proposed definition refers only to "food," not "food for consumption." This causes the problem of sweeping packaging, packaging component, and raw material facilities within the scope of the regulation. Clearly, this was not the intent of Congress. FDA should correct this inappropriate definition, and replace it with a definition of "food for consumption" for purposes of the registration provisions to exclude packaging materials, food contact articles, and the raw materials used to make them. Doing so is consistent with the clear language of the authorizing legislation and FDA's mandate to ensure the safety of the United States food supply in the least burdensome means possible.

I. FDA's Proposed Inclusion of Food Packaging, Other Food Contact Substances, and Raw Materials in the Definition of "Food" is Not Consistent with Congressional Intent

Section 305 of the Bioterrorism Act requires registration of any facility engaged in manufacturing, processing, packing or holding "food for consumption" in the United States. Because the statute included the modifying phrase "for consumption in the United States," manufacturers of food packaging and other food contact articles and their suppliers, including APC and PSPC members, were not concerned that this requirement could be applied to anything other than food that is actually consumed. It was thought that FDA would abide by the statutory language that requires application of this provision only to food that is actually consumed.

For purposes of its proposed regulations, FDA has proposed to use a very broad definition of "food" rather than the appropriate term "food for consumption." In direct opposition to the explicit statutory language, FDA has proposed to define "food" to encompass all articles within its statutory jurisdiction under section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This ignores the explicit congressional mandate to apply this requirement only to "food for consumption." FDA provides examples of products that are technically considered "food" under the FD&C Act, including "substances that migrate into food from food packaging and other articles that contact food." 68 Fed. Reg. 5378, 5382 (February 3, 2003). Including these substances ignores the explicit instructions from Congress. If FDA is permitted to ignore the express language of the statute in this manner, there is no obvious limit to the facilities to which it could apply the registration requirement. Any facility engaged in the manufacture, processing, packing, or holding of any component of food packaging or any other food contact

material, or any of their suppliers, could be subjected to the registration requirement, as any ingredient of anything that may migrate into food would be considered a "food" under FDA's interpretation. None of these materials, however, is a "food for consumption."

Section 305 of the Bioterrorism Act states that FDA may, through guidance, require the category of food (as defined in 21 C.F.R. 170.3) the facility handles to be included on the registration. There is no category for food packaging or other food contact articles and their components. This is yet further evidence that Congress did not intend packaging and other food contact articles to be included in the definition of "food for consumption" for purposes of the registration requirement. FDA's proposed registration requirement, when applied to food packaging or other food contact material facilities, will have no benefit for the safety of the food supply.

In a small attempt to exclude articles that have absolutely no food contact, FDA states in the preamble that "Substances that migrate into food from food packaging include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food." 68 Federal Register 5382. This language is not consistent with FDA's prior "functional barrier" interpretations, where the mere presence of an intervening layer is not *per se* sufficient to claim no migration. This exclusion may be more properly stated as "outer packaging separated from food by a functional barrier is not considered a substance that migrates into food." Even so, this exclusion accomplishes nothing. Packaging and packaging components that do not migrate into food are obviously not within FDA's jurisdiction and thus do not even need to be excluded. Regardless

of this "exclusion," tens of thousands of chemicals and food contact articles will still be required to be manufactured in a registered facility.

Because the registration requirement is for the entire facility, FDA's proposed interpretation will cause nearly every facility operated by APC and PSPC member companies to register. Even if only a small percentage of the output of a facility is for food use, the entire facility must be registered. Because there are very few, if any, "non-food use only" facilities, this will result in the registration of nearly every facility.

Congress directed that FDA should exercise "discretion in the development and implementation of registration regulations to ensure that registration requirements are neither burdensome nor disruptive of the smooth flow of commerce." 148 Cong. Rec. H2858 (daily ed. May 22, 2002) (statement of Rep. Shimkus). Imposing the registration requirement to facilities beyond the scope anticipated by Congress violates this congressional instruction.

FDA, as the agency authorized to implement the provisions of the Bioterrorism Act, has discretion in interpreting the terms in that legislation, when interpretation is required. Where the statute is clear, however, FDA is bound by the language of the statute and clear expressions of congressional intent. When Congress has spoken directly to an issue, the agency (and any reviewing court) must give effect to the unambiguously expressed intent of Congress. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000). Here,

Congress specifically included the language "for consumption in the United States" to qualify "food" for purposes of the definition of facilities to which the registration requirement applies.

FDA's proposed inclusion of food packaging and food contact materials in the definition of "food for consumption in the United States" for purposes of the registration requirement ignores the explicit statutory language. Packaging and other food contact articles are, quite simply, not consumed. It is well settled that statutes should be interpreted in a manner to give effect to all words in the statute. Thus, FDA should revise its definition of "food" to give effect to the "for consumption" language, and exclude items such as food packaging and food contact articles, which may technically fall within the statutory definition of food, but clearly are not intended "for consumption in the United States."

II. Subjecting Food Packaging and Food Contact Substances to Registration Will Not Further the Purposes of the Bioterrorism Act

The Conference Report on the Bioterrorism Act states that the intent of the bill is "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." H. R. Rept. No. 107-481, 107 Cong., 2d Sess., Joint Statement of the Committee on Conference (May 21, 2002), p. 107. Consequently, all the requirements imposed by the Act must be aimed at achieving this goal. While many of the provisions of the Bioterrorism Act, when applied to conventional food, will further this purpose, they will not do so when applied to food packaging and other food contact materials.

The potential list of food contact articles is tremendous. For example, the broad array of materials FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, reveals the scope of materials FDA considers "food" under the statute. These regulations do not cover articles typically referred to as "housewares," which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments. These items have traditionally been considered outside the scope of FDA's food additive authority, but are still considered "food." Under FDA's proposed definition of "food" for purposes of the registration requirement, however, all facilities manufacturing, processing, packing, or holding these articles, and any of their components, require registration. Thus, all firms engaged in any of these industries would be subject to registration: paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, as well as all utensils. None of these could reasonably be considered "food for consumption."

Applying the registration requirement to this broad variety of products will overwhelm both industry and FDA resources, with no benefit as far as increased security for the United States food supply. It is difficult to believe that a terrorist attack on the food supply will be carried out through packaging. As a technical matter, it would be virtually impossible to insert a poison in packaging with a sustained release mechanism to contaminate food, without the full cooperation of the packaging manufacturer. Even putting aside the technical and logistical complexities that would be involved, such an indirect approach would have virtually no impact before discovery. Packaging manufacturers and food processors have routine procedures in place to ensure that

their packaging materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage.

FDA has stated in public meetings that one of the purposes of the registration requirement is to allow FDA to notify facilities engaged in a particular food sector of a threat to that sector. Comments of Robert Lake, FDA Satellite Video Conference, January 29, 2003. This simply does not apply to packaging and other food contact material facilities. If, for example, FDA were to receive credible information of a threat to the packaged cereal supply, FDA would notify the cereal manufacturers. FDA would not, and should not, attempt to identify the facilities engaged in the manufacture, processing, packing or holding of cereal packaging. That would be an absurd waste of FDA's valuable resources. Whenever it would be relevant for a food packaging facility to be contacted because of a threat to the food supply, it will be because a conventional food is involved. Conventional food facilities maintain records regarding their suppliers, including packaging and other food contact material suppliers, in the normal course of business, so the processor would be able to notify their suppliers or provide the information to FDA at that time. There is no benefit to FDA maintaining an independent database of these facilities, as FDA would, of necessity, first contact the food facility.

FDA has previously identified the insignificance of food packaging and other food contact articles in the realm of protecting against intentional attacks on the food system. When FDA established its guidance for industry of measures to increase the security of the food supply, the guidelines were directed at conventional food facilities. Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance; CFSAN, January 9,

2002. No mention was made of packaging facilities. In fact, packaging was mentioned merely as one of the items for which the food facility should establish procedures. FDA has maintained this separation in its Final Guidance, made available on March 21, 2003. 68 Fed. Reg. 13931. Thus, if a food establishment follows these FDA guidelines, any possible threat to the food supply from the packaging or any other food contact material will already be identified by the food establishment. This guidance document demonstrates the futility of applying the registration requirement to food packaging and other food contact substance facilities as FDA proposes in this regulation.

III. FDA Underestimates the Burden of the Proposed Regulation

In estimating the cost of the registration requirement, FDA focused on firms in several primary industries. Within these industries, FDA estimates that 22,000 facilities will be required to register. 68 Fed. Reg. at 5391. FDA's estimate, however ignores several aspects that result in an underestimate of the burden imposed. The first is the wide range of "upstream" manufacturers that make ingredients and components that go into food packaging and other food contact articles. Given FDA's willingness to extend the definition of "food" beyond the clearly expressed congressional intent to everything that may possibly be considered "food" under the FD&C Act, any ingredient of any of these items could subject the facility from which it came to registration. This paperwork and logistical burden will be immense, with no commensurate increase in safety of the United States food supply.

The immense burden will fall not only on large plastic and industrial chemical companies. Many of the facilities are small, independent establishments. Also, the recycling industry will be affected, as many food contact articles make use of recycled input. Taking FDA's definition of food, any facility that manufactures, processes, packs, or holds a material that could become a component of packaging or other food contact article would be required to register. And any supplier of ingredients to manufacturers of any of these items would be required to register. There is no logical conclusion to this chain, which is why Congress wisely inserted one into the legislation. Only facilities that manufacture, process, pack, or hold food for consumption in the United States must register. Because the burden of this legislation could quickly outweigh the benefits unless reasonable limits are imposed, Congress wisely limited the registration requirement FDA is underestimating the burden it will impose by ignoring that language in its proposal.

Given the extraordinarily high cost of this proposal, FDA should focus its resources where there is the opportunity to benefit the safety of the United States food supply - food itself. There is no benefit to applying the registration requirements to food packaging and other food contact article facilities, and doing so amounts to nothing more than a waste of limited resources. FDA has been tasked with an immense obligation, ensuring the safety of the United States food supply, and it must focus its resources on areas where the expenditure of resources will yield returns in increased safety. Registration of food packaging and other food contact article facilities will not achieve this purpose.

With FDA's proposed requirements for updating the registration within thirty days of any change in the information on the registration, coupled with the extensive list of information required for the registration, FDA is essentially creating a monthly registration requirement. It is entirely foreseeable that at least one element of the information on the registration could change each month, thereby necessitating an update to the registration. Also, given the requirement to update within thirty days, all companies must review their registration at least once every thirty days to ensure the information remains accurate. This will impose an immense burden in personnel-hours, and one that was not accurately captured in the proposal.

The examples of foodborne outbreaks to which FDA refers in the preamble that could be averted by these requirements have nothing to do with food packaging. Beginning on page 5409 of the preamble, FDA sets out the cost of five foodborne outbreaks. The "vehicles" for these outbreaks are all conventional foods, and have nothing to do with packaging or other food contact articles. If FDA seriously thinks that food packaging or other food contact articles pose a potential threat from an intentional attack on the food supply, FDA would have estimated the cost of such an attack, in an attempt to justify the immense burden being placed on the industry. In the absence of such an estimate, FDA's treatment of food packaging and other food contact materials is completely unjustified.

IV. Conclusion

FDA should replace its definition of "food" with a more appropriate definition of "food for consumption" for purposes of the registration requirement to exclude food packaging and other

food contact articles as they are clearly not "food for consumption." Doing so is consistent with explicit statutory language, congressional intent, and FDA's mission to protect the safety of the United States food supply under the Bioterrorism Act.

Respectfully submitted,

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